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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,875	03/08/2004	Keith G. Lurie	016354-005213US	2670
20350 7590 07/21/2009 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834				
EXAMINER				
PATEL, NIHIR B				
ART UNIT		PAPER NUMBER		
3772				
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07/21/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/796,875

Applicant(s)

LURIE ET AL.

Examiner

NIHIR PATEL

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/15/2009 (petition decision).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 01.03.2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 1st, 2008 has been entered.

Affidavits/Declarations

2. The Affidavit filed on September 10th, 2007 under 37 CFR 1.131 is sufficient to overcome the abandonment filed on August 6th, 2007.

Terminal Disclaimer

3. The terminal disclaimer filed on October 19th, 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,938,618 and any patent granted on application 10/660,462 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

4. Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection.

5. The petition to revive the current applicant was granted and the abandonment has been withdrawn. Prosecution in the current application is reopened.

Response to Amendment

6. The examiner acknowledges the amendment filed on October 1st, 2008. The amended comprises amending claims 1, 17 and 24.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims **17-21 and 23** are rejected under 35 U.S.C. 102(b) as being anticipated by Weisfeldt et al. (US 4,397,306).
9. **As to claim 17**, Weisfeldt teaches an apparatus that comprises a means to interface with the patient's airway **12 (see figs. 4 and 5; col. 4 lines 10-20)**; a means to repeatedly extract respiratory gases from the patient's lungs and airway to create and periodically maintain a negative intrathoracic pressure **(see col. 4 lines 15-25; col. 5 lines 15-30)**; a means to repeatedly regulate the extraction of respiratory gases within the patient's lungs and airway **(see col. 4 lines 15-25; col. 5 lines 15-30)**; and a means to deliver a positive pressure breath, to periodically provide inspiration of respiratory gases **(see col. 4 lines 10-40 and col. 5 lines 15-40)**.

10. **As to claim 18**, Weisfeldt teaches an apparatus wherein the means to extract respiratory gases comprises vacuum source selected from a group consisting of a suction line or venturi device to an oxygen tank (**see col. 4 lines 10-23**).
11. **As to claim 19**, Weisfeldt teaches an apparatus that further comprises a switching mechanism to stop the extraction of respiratory gases during delivery of a positive pressure breath, wherein the switching mechanism is selected from a group consisting of mechanical devices, magnetic devices, and electronic devices (**see col. 4 lines 51-55**).
12. **As to claim 20**, Weisfeldt teaches an apparatus wherein the means for extracting respiratory gases is selected from a group consisting of a mechanical ventilator, a vacuum with vacuum regulator, a phrenic nerve stimulator, an extrathoracic vest, a ventilator bag, and an iron lung cuirass device (**see col. 4 lines 10-23**).
13. **As to claim 21**, Weisfeldt teaches an apparatus wherein the means for regulating comprises a threshold valve that is in fluid communication with the person's airway (**see col. 4 lines 28-39**).
14. **As to claim 23**, Weisfeldt teaches an apparatus wherein the means for delivering a positive pressure breath is selected from a group consisting of a mechanical ventilator, a hand held bag valve resuscitator, mouth-to-mouth, or a means to provide intermittent positive pressure ventilation (**see col. 4 lines 10-23**).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims **1-16 and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Weisfeldt et al. (US 4,397,306).

18. **As to claims 1, 4, 10, 14-16 and 22**, Weisfeldt substantially discloses method steps of delivering a positive pressure breath to the person (see **col. 5 lines 15-25**); extracting respiratory gases from the person's airway using a vacuum following the positive pressure breath to create an intrathoracic vacuum to lower pressures in the thorax to maintain a negative pressure (see **col. 5 lines 20-30**) and to enhance blood flow back to the heart (see **col. 2 lines 20-30**); and repeating the steps of delivering positive pressure breaths and extracting respiratory gases to thereby treat said person suffering from said ailment (see **col. 2 lines 55-68 and col. 3 lines 1-4**), but does not disclose maintaining a negative pressure between 0 mmHg to about -50 mmHg. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Weisfeldt's invention by providing a negative pressure between 0 mmHg to about -50 mmHg in order to extract the proper amount of respiratory gases within the patient, since it has been held that where the general conditions of a claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*,
105 USPQ 233.

19. **As to claim 2**, Weisfeldt substantially discloses method steps wherein the person is suffering from an ailment from a group consisting of head trauma, elevated intracranial pressures, low blood pressure; low blood circulation, low blood volume, cardiac arrest, hypotension, shock, hypertension, intraocular pressures and heat failure (**see col. 3 lines 20-30**).

20. **As to claim 3**, Weisfeldt substantially discloses method steps regulating the amount of intrathoracic vacuum using a threshold valve that is in fluid communication with the person's airway (**see col. 4 lines 28-39**).

21. **As to claim 5**, Weisfeldt substantially discloses method steps of stopping application of the vacuum when applying the positive pressure breath using a switching arrangement (**see col. 4 lines 51-55**).

22. **As to claim 6**, Weisfeldt substantially discloses method steps wherein the positive breath is delivered using source selected from a group consisting of a mechanical ventilator, a hand held bag valve resuscitator, mouth-to-mouth, or a means to provide intermittent positive pressure (**see col. 4 lines 10-23**).

23. **As to claim 7**, Weisfeldt substantially discloses method steps wherein the respiratory gases are extracted with a constant extraction, varied over time or pulsed extraction (**see col. 5 lines 20-30**).

24. **As to claim 11**, Weisfeldt substantially discloses method steps wherein the vacuum is maintained with negative flow or without flow (**see col. 5 lines 20-30**).

25. **As to claim 13**, Weisfeldt substantially discloses method steps wherein the respiratory gases are extracted using equipment selected from a group consisting of a mechanical ventilator, a vacuum with vacuum regulator, a phrenic nerve stimulator, an extrathoracic vest, a ventilator bag, and an iron lung cuirass device (see col. 4 lines 10-23).

26. **As to claim 8**, Weisfeldt substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose breath being delivered for a time in the range for about 250 milliseconds to about 2 second. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Weisfeldt's invention by providing a breath being delivered for a time in the range for about 250 milliseconds to about 2 second in order to provide the patient with the correct amount of ventilation, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

27. **As to claim 9**, Weisfeldt substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a breath that is delivered at a rate in the range from about 0.1 liters per seconds to about 5 liters per second. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Weisfeldt's invention by providing a breath that is delivered at a rate in the range from about 0.1 liters per seconds to about 5 liters per second in order to provide the patient with the correct amount of ventilation, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

28. **As to claim 12**, Weisfeldt substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose the time the positive pressure breath is supplied relative to the time in which respiratory gases are extracted is in the range from about 0.5 to about 0.1. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Weisfeldt's invention by providing the time the positive pressure breath is supplied relative to the time in which respiratory gases are extracted is in the range from about 0.5 to about 0.1 in order to provide the patient with the correct amount of ventilation, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

29. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weisfeldt et al. (US 4,397,306) in view of Abramov et al. (US 5,806,512).

30. **As to claim 24**, Weisfeldt substantially discloses a vacuum source in fluid communication with the housing for repeatedly extracting respiratory gases from the person's lungs and airway to create and periodically maintain a negative intrathoracic pressure (see col. 4 lines 20-30 and col. 5 lines 20-30); a vacuum regulator to regulate the extraction of respiratory gases from the patient's lungs and airway (see col. 4 lines 28-39); and a positive pressure source in fluid communication with the housing for intermittently supplying positive pressure breaths to the person (see col. 4 lines 10-30 and col. 5 lines 15-30) but does not disclose a housing having an interface that is adapted to couple the housing to the person's airway. Abramov teaches an apparatus that does disclose a housing 38 (see fig. 1) having an interface that is adapted to couple the housing to the person's airway in order to prevent leakage.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772
/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772

